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Filed : August 16, 2001

## REMARKS

Claims 22-26 and 33-37 are pending as set forth above. New Claims 35-40 have been added. The subject matter of Claims 35-37 was previously presented as Claims 27-29, which were previously cancelled without prejudice in the amendment filed on November 20, 2003, in order to advance the application to allowance. New Claims 38-40 are supported by the application as filed, for example, particularly Figure 2 and page 66, line 26 to page 67, line 14. No other claim amendments have been made and no new matter has been added. The only pending rejection is the rejection under 35 U.S.C. § 102(e), which is discussed below.

### Correction of Inventorship under 37 C.F.R. § 1.48(b) (Deletion of Inventors)

Due to the previous amendments to the claims, amendment of the inventorship is requested as set forth in the “Request to Correct Inventorship Under Rule § 1.48(b),” on page 5 of this paper.

### Rejection under 35 U.S.C. §102(e)

Claims 22-26 and 33-34 were rejected under 35 U.S.C. § 102(e) as being anticipated by Piddington et al., U.S. Patent No. 6,521,233 (referred to hereafter as “Piddington”). Attached herewith is the Declaration of Luc Desnoyers and William I. Wood under 37 C.F.R. §1.131 (referred to hereafter as “the Declaration of Desnoyers and Wood”). The Declaration of Desnoyers and Wood establishes that the presently claimed subject matter was conceived prior to the earliest effective date of Piddington, April 20, 1999, and reduced to practice after the Piddington effective publication date by diligent efforts commencing before April 20, 1999.

As set forth in 37 C.F.R. § 1.131, a patent applicant “may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.” *See also*, M.P.E.P. § 715. “The affidavit or declaration must state FACTS and produce such documentary evidence and exhibits in support thereof as are available to show conception and completion of the invention in this country … at least conception being at a date prior to the effective date of the reference.” *See* M.P.E.P. § 715.07 (emphasis in original). The showing of facts must be sufficient to show “conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice.” *See id.*

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Piddington is based upon a nonprovisional application that was filed on April 19, 2000, but which claimed priority to U.S. Provisional Application No. 60/130,199, which was filed on April 20, 1999. Therefore, the earliest effective publication date of Piddington is April 20, 1999. Piddington is cited as a 102(e) reference because it allegedly discloses the complete sequence of SEQ ID NO:2 from the instant application. However, as set forth below, Applicants were in possession of SEQ ID NO:2 prior to the effective publication date of Piddington.

The Declaration and attached Exhibit A demonstrate that the claimed subject matter, particularly a polypeptide having the sequence of SEQ ID NO:2, was conceived by Applicants prior to April 20, 1999. Furthermore, as evidenced by the Declaration and Exhibit B-D, Applicants exhibited diligence in reducing the subject matter of the claims to practice from at least just prior to the Piddington effective date, by performing various assays to confirm the function of the polypeptide. Finally, as demonstrated by Exhibits D and E, the subject matter of the claims was reduced to practice on November 10, 1999. The Declaration and Exhibits are discussed in further detail below.

#### *Conception of SEQ ID NO:2*

Prior to April 20, 1999, the idea of investigating several newly discovered polypeptide sequences for their relevance was conceived. Exhibit A is a sequence map showing a polypeptide having the full sequence of SEQ ID NO:2. As set forth in the attached Exhibit A, Applicants possessed the entire sequence of SEQ ID NO:2 at a date prior to April 20, 1999.

#### *Diligence in Reducing the Claimed Subject Matter to Practice*

After obtaining the polypeptide having the sequence of SEQ ID NO:2, Applicants worked diligently to reduce the claimed subject matter to practice. The cDNA was deposited with the American Type Culture Collection (ATCC) on January 12, 1999 and assigned ATCC no. 203581. As evidenced by Exhibits B-D, Applicants worked systematically to express and purify the polypeptide and to run it through a large number of assays. As evidenced by Exhibit B, the polypeptide was expressed in *E. coli*, *Baculovirus*, and in mammalian cells. Also, various constructs with tags, such as poly-His or IgG tags, were made from the time of first cloning. The construction of these was followed by expression and purification of the protein during the time period of prior to April 20, 1999 through March 13, 2003. Exhibit C shows one such purification

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that was completed on July 13, 1999. The purified proteins were distributed to various scientists for multiple cell-based assays and/or quality confirmation tests from August 20, 1999 through January 22, 2001. Many of the assays are listed on Exhibits D and E. Thus, Applicants showed diligence from prior to April 20, 1999 up until an actual reduction practice, which occurred on November 10, 1999 as explained more fully below.

*Reduction to Practice*

Exhibit D demonstrates, at least in part, the large variety of assays performed as part of the large screening system for the polypeptide. Exhibit E shows the results of several chondrocyte redifferentiation assays demonstrating a function for the claimed polypeptide. For one of the assays, samples of the polypeptide were distributed to the inventor on October 22, 1999, and the assay was completed on November 10, 1999 with results demonstrating the activity of the polypeptide. Therefore, the claimed polypeptides were reduced to practice at least by November 10, 1999.

As set forth above, and as evidence by the attached Declaration under § 1.131 with the accompanying exhibits, Applicants conceived the claimed subject matter prior to April 20, 1999, then worked diligently from before April 20, 1999, until November 10, 1999 to reduce the claimed polypeptide to practice.

Thus, Piddington does not anticipate Claims 22-26 and 33-40 because Applicants conceived the claimed subject matter prior to the effective publication date of Piddington, and thereafter diligently reduced it to practice. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims under 35 U.S.C. § 102(e) over Piddington.

**Conclusion**

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, the arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a



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telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 5/21/04

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